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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,642	02/01/2002	Richard Fayrer-Hosken	235.00310101	1056
26813	7590	02/23/2006	EXAMINER	
MUETING, RAASCH & GEBHARDT, P.A. P.O. BOX 581415 MINNEAPOLIS, MN 55458			SZPERKA, MICHAEL EDWARD	
			ART UNIT	PAPER NUMBER
			1644	
DATE MAILED: 02/23/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/019,642

Applicant(s)

FAYRER-HOSKEN ET AL.

Examiner

Michael Szperka

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-5, 7-11 and 17-39 is/are pending in the application.
- 4a) Of the above claim(s) 17-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-5, 7-11 and 29-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/22/05</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's response and amendments received November 28, 2005 are acknowledged.

Claims 1, 6, and 12-16 stand canceled.

Claims 35 and 36 have been amended.

Claims 2-5, 7-11, and 17-39 are pending.

Claims 17-28 stand withdrawn for the reasons set forth in the office action mailed September 22, 2004.

Claims 2-5, 7-11, and 29-39 are under examination as they relate to a fertility impairing vaccine containing avian zona pellucida protein in the instant office action.

### ***Information Disclosure Statement***

2. The IDS received March 22, 2005 was previously acknowledged and considered as was indicated in the office action mailed May 26, 2005. The examiner apologizes for improperly marking this information on the form returned with the office action, and a copy of said form with the appropriate notation accompanies this office action.

***Election/Restrictions***

3. Applicant continues to traverse the restriction requirement mailed July 1, 2004.

This requirement was made final in the office action mailed September 22, 2004 and will not be addressed further.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 2-5, 7-11, and 29-39 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed for the reasons of record set forth in the office actions mailed September 22, 2004 and June 28, 2005.

Applicant's arguments filed November 28, 2005 on pages 8 and 9 of the response have been fully considered but they are not persuasive. Applicant repeats the argument of record that because the specification defines an immunogenic fragment of a zona pellucida protein as a fragment that elicits an immune response when administered to an animal the burden of adequate written description has been met, and further argues that full length protein can be used as a starting material and that the

specification teaches screening methods that can be used to identify immunogenic fragments.

The examiner agrees that it may be possible to screen for such immunogenic fragments using the teachings of the specification. However, the guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species, then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3). The specification does not disclose any members of the genus of immunogenic fragments, hence applicant's arguments that the specification is enabling for how to screen for such fragments. While such a screening assay might allow a skilled artisan to discover immunogenic fragments of a zona pellucida protein, the claimed invention still lacks adequate written description of the claimed invention. As has been stated in previous office actions, applicant has not pointed to a specific region or regions of zona pellucida protein that provide a structure that gives rise to the function of being immunogenic, and no members of this genus have been disclosed. As such, while applicant has possession of full length zona pellucida protein isolated from chicken, applicant is not in

possession of the genus of immunogenic fragments of zona pellucida protein.

Therefore, the rejection of record is maintained.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 37 and 38 stand rejected under 35 U.S.C. 102(a) as being anticipated by Waclawek et al. (Biology of Reproduction, 1998; 59:1230-1239, reference C90 on Applicant's IDS dated 2/14/03, see entire document) for the reasons of record set forth in the office action mailed June 28, 2005.

Applicant's arguments filed November 28, 2005 have been fully considered but they are not fully persuasive. The examiner agrees that the limitations recited in claims 35 and 36 as amended November 28, 2005 are not taught by Waclawek et al. and as such they have been removed from the rejection. The examiner also agrees that while Waclawek et al. teach many zona pellucida antigens of multiple sizes, none of these appear to be 70kDa. The examiner disagrees that Waclawek et al. do not teach polypeptides of 35 and 40 kDa. As was indicated previously, the chZPC isolated by Waclawek et al. is heterogeneous in size, with sizes ranging from 34-43 kDa (see particularly Figures 1, 5, 8, and 9). As such the chZPC preparation of Waclawek et al.

contains polypeptides of 34 and 40 kDa and meets the limitations of the claims.

Further, applicant's own specification teaches in lines 6-9 of page 15 that the 35 kDa, the 40 kDa, or both the 35 and 40 kDa are likely to be ZPC.

As such, the rejection of record is maintained.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 2-5, 10, 11, 29, 31, and 32 stand rejected and claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wacławek et al. (Biology of Reproduction, 1998; 59:1230-1239, reference C90 on Applicant's IDS dated 2/14/03, see entire document) in view of Cox et al. (Vaccine, (1997) 15:248-256, see entire document, cited as document U on form 892 mailed May 26, 2005) for the reasons of record set forth in the office action mailed June 28, 2005.

Applicant's arguments filed November 28, 2005 have been fully considered but they are not persuasive. Applicant argues that there is no motivation in either reference to use the claimed invention, bird zona pellucida protein in particular adjuvants, as a vaccine. Waclawek et al. administer bird zona pellucida protein in combination with adjuvant to induce an antibody response, and applicant's vaccine is also intended to induce an antibody response in the recipient. The recitation of the composition (ZP antigen + adjuvant) as a vaccine provides an intended use for the composition and does not alter the structure or ingredients of the resulting composition. As such, the recitation of the claimed composition as a vaccine has not been accorded patentable weight. Applicant is also reminded that the motivation to combine need not be the same as the motivation taught by applicant in the instant application. Applicant amended claims 35 and 36 on November 28, 2005 to include the limitation of adjuvants not taught in the art of Waclawek et al. by changing their dependency to depend from claim 29, and as such they are properly part of this rejection.

Therefore, the rejection is maintained.

10. Claims 2-5, 7, 8, 10, 11, 29, 31, and 33 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Waclawek et al. (Biology of Reproduction, 1998; 59:1230-1239, reference C90 on Applicant's IDS dated 2/14/03, see entire document) in view of Willis et al. (J. Equine Vet. Sci, (1994) 14:364-370, reference C92 on Applicant's IDS dated 2/14/03, see entire document) for the reasons of record set forth in the office action mailed June 28, 2005.



Applicant's arguments filed November 28, 2005 have been fully considered but they are not persuasive. Applicant argues that there is no motivation to combine the references based upon the intended use of the composition. This argument has been addressed supra and will not be discussed further.

The rejection is maintained.

11. Claim 30 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Waclawek et al. (Biology of Reproduction, 1998; 59:1230-1239, reference C90 on Applicant's IDS dated 2/14/03, see entire document) in view of Dean (US Patent 5,641,487, of record as reference A22 on Applicant's IDS dated 2/14/03, see entire document) for the reasons of record set forth in the office action mailed June 28, 2005.

Applicant's arguments filed November 28, 2005 have been fully considered but they are not persuasive. Applicant continues to argue intended use which has already been discussed supra. Applicant also argues that Waclawek et al. do not teach immunization with fragments. Applicant is reminded that the claim recites "avian zona pellucida protein or an immunogenic fragment thereof" and as such the question of Waclawek et al. teaching fragments of their protein is not relevant.

The rejection is maintained.

12. Claims 9 and 39 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Waclawek et al. (Biology of Reproduction, 1998; 59:1230-1239, reference C90 on Applicant's IDS dated 2/14/03, see entire document) in view of Bagavant et al. (Biology

of Reproduction (1997), 56:764-770, of record as reference C5 on Applicant's IDS dated 2/14/03, see entire document) for the reasons of record set forth in the office action mailed June 28, 2005.

Applicant's arguments filed November 28, 2005 have been fully considered but they are not persuasive. Applicant continues to argue intended use which has already been discussed supra. Applicant also argues that Wacławek et al. do not teach chicken ZPC fragments. The claims recite "avian zona pellucida protein or an immunogenic fragment thereof" and as such Wacławek et al. do not need to teach fragments of chZPC.

The rejection is maintained.

13. No claims are allowable.

14. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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